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EXAMINER

YOON, TAE H

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1714

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/673,041

Applicant(s)

SOHIER ET AL.

Examiner

Tae H. Yoon

Art Unit

1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

The recited "preferably ---" in claims 6-8, "such as" in claim 10 and "e.g." in claim 21 are objected and separation claims with said narrow limitations are suggested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 10-14 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "porous" in claim 14 is confusing since the coating of claim 1 is directed to the coating before application on a medical device as evidenced by claim 15, and thus said coating cannot be porous. Line 23, page 5 of the specification teaches that a surface being coated is porous. Lines 18-23, page 16 of the specification teaches that a porous coating is formed by utilizing a pore-forming agent with a coating (before application).

Improper Markush language is recited in 2, 4, 10-13 and 21, and an insertion of "consisting" between "the group" and "of" is needed.

It is unclear what are "materials for approximation" in line 3 of claim 21.

The intended use (for a medical device) has no probative value, and the recited preamble (a coating) also has no probative value absent further limitation defining said coating. The examiner interprets the copolymer as well as a coating being claimed.

Art Unit: 1714

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 6,685,957. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly recited coating has little probative value absent further limitation and the instant medical device encompasses the implant of said patent.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 1714

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 20 and 21 are rejected under 35 U.S.C. 102(a) as anticipated by WO 01/10478.

WO teaches the instant poly(ethylene oxide)terephthalate/poly(1,4butylenes)terephthalate and molecular weights and a solution thereof at pages 1-3 and in examples. The utilization of proteins and other biologically active agents is taught at page 7. The recited substrates in claims 12 and 13 have no probative value since they are not claimed limitation when said claims 12 and 13 are combined with claim 1 wherein a medical device is an intended use. Also, the molded article of WO meets the medical device of claims 20 and 21.

Thus, the instant invention lacks novelty.

Claims 1-7 and 9-14 are rejected under 35 U.S.C. 102(b) as anticipated by Goedemoed et al (US 5,980,948).

Goedemoed et al teach the instant poly(ethylene oxide)terephthalate/poly(1,4butylenes)terephthalate in example 1 wherein molecular weights such as 1,000 of polyethylene glycols also seen. Polymeric particles loaded

Art Unit: 1714

with protein are taught at col. 16, lines 28-44. Also, the water-in-oil emulsion and solution taught at col. 16, lines 28-49 meet the coating. The recited substrates in claims 12 and 13 have no probative value since they are not claimed limitation when said claims 12 and 13 are combined with claim 1 wherein a medical device is an intended use. The porous particles taught at col. 16, lines 55-61 meet the claim 14.

Thus, the instant invention lacks novelty.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as obvious over Goedemoed et al (US 5,980,948) in view of WO 01/10478 or Bakker et al (US 2002/0095213 A).

Claim 8 further recites weight average molecular weight of the copolymer over Goedemoed et al who do not specify such molecular weight. However, Goedemoed et al teach employing polyethylene glycols having the same molecular weights, and the copolymer having the instant molecular weight is well known as taught by WO (page 3) or Bakker et al ([0105]).

It would have been obvious to one skilled in the art at the time of invention to utilize the recited weight average molecular weight of the copolymer in Goedemoed et al with teaching of WO or Bakker et al since the molecular weights of the polyethylene glycol are the same and thus the use of said polyethylene glycol would yield a similar molecular weight and since Goedemoed et al teach other polymers having the instant molecular weight at col. 15, lines 59 and 65 and since the copolymer having the instant molecular weight is well known absent showing otherwise.

Art Unit: 1714

Claims 1-7, 9-14, 20 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by Bakker et al (US 5,480,436).

Bakker et al teach the instant poly(ethylene oxide)terephthalate/poly(1,4butylenes)terephthalate in abstract, col. 5, lines 31-51 and examples 1 and 3. The molecular weight such as 1,000 of polyethylene glycol is also seen in example 1. Medical devices having a double-layered structure containing various biologically active agents are taught in abstract, col. 1, line 51 to col. 2, line 6, col. 5, line 63 to col. 6, line 14, col. 11, lines 7-67 and in examples.

Thus, the instant invention lacks novelty.

Claims 1-14, 20 and 21 are rejected under 35 U.S.C. 103(a) as obvious over Bakker et al (US 5,480,436) in view of WO 01/10478 or Bakker et al (US 2002/0095213 A).

Claim 8 further recites weight average molecular weight of the copolymer over Bakker et al (US'436) who do not specify such molecular weight. However, Bakker et al (US'436) teach employing polyethylene glycols having the same molecular weights and copolymers are biodegradable, and the copolymer having the instant molecular weight is well known as taught by WO (page 3) or Bakker et al ([0105] of US'213).

It would have been obvious to one skilled in the art at the time of invention to utilize the recited weight average molecular weight of the copolymer in Bakker et al (US'436) with teaching of WO or Bakker et al (US'213).and since the molecular weights of the polyethylene glycol are the same and thus the use of said polyethylene glycol

would yield a similar molecular weight and since Bakker et al (US'436) teach that copolymers are biodegradable requiring a reasonable molecular as claimed and since the copolymer having the instant molecular weight is well known absent showing otherwise.

Claims 1-9, 12-15 and 17-21 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bakker et al (US 2002/0095213 A).

Bakker et al teach the instant poly(ethylene oxide)terephthalate/poly(1,4butylenes)terephthalate in abstract and examples. The molecular weight such as 1,000 of polyethylene glycol is also seen in example 1. The instant molecular weights of copolymers are seen in table of [0105]. Medical devices produced by coextrusion method yielding the instant coated medical devices are taught in [0088]. The use of said copolymer as coatings for prosthetic devices are seen in [0092] and [0093], and said coating would be either a solution or suspension inherently depending on the solvent used. Various substrates and devices are seen in [0070] and [0075].

Thus, the instant invention lacks novelty.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as obvious over Bakker et al (US 2002/0095213 A) in view of Bakker et al (US 5,480,436), Goedemoed et al (US 5,980,948), WO 01/10478 or EP 0 830 859.



The instant invention further recites employing proteins and other biologically active agents and cleaning the surface of the substrate over Bakker et al (US'213 A). However, the utilization of proteins and other biologically active agents in medical devices used in human's body is well known practice as taught by Bakker et al (US'436) Goedemoed et al and WO. EP also teaches such in abstract. Also, cleaning of the surface of the substrate before coating in order to obtain a better adhesion between coating and surface is a routine practice in the art.

It would have been obvious to one skilled in the art at the time of invention to clean the surface of the substrate or to utilize the art well known proteins and other biologically active agents taught by Bakker et al (US'436), Goedemoed et al, WO or EP in the coating composition of Bakker et al (US'213 A) since the utilization of proteins and other biologically active agents in medical devices used in human's body is well known practice and since cleaning of the surface of the substrate before coating in order to obtain a better adhesion between coating and surface is a routine practice in the art.

Claims 1-14, 20 and 21 are rejected under 35 U.S.C. 102(e) as anticipated by Bezemer et al (US 6,685,957).

Bezemer et al teach the protein loaded W/O emulsion of the instant poly(ethylene oxide)terephthalate/poly(1,4butylenes)terephthalate at col. 12, lines 55-58 and col. 13, lines 36-48, and said emulsion meets the coating. The molecular weights are taught at col. 3, lines 29-46. Thus, the instant invention lacks novelty.

Art Unit: 1714

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tae H. Yoon whose telephone number is (571) 272-1128. The examiner can normally be reached on Mon-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tae H Yoon  
Primary Examiner  
Art Unit 1714

THY/September 16, 2005